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APPLICATION FOR LETTERS PATENT

for

MECHANICAL OCCLUDING AND DILATION DEVICE FOR A VESSEL

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MECHANICAL OCCLUDING AND DILATION DEVICE FOR A VESSEL

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BACKGROUND OF THE INVENTION

1. Field of the Invention.

The present invention relates to mechanical occluding devices. More particularly, the present invention is directed to a vaso-occluding stent for occluding blood flow to a benign tumor or similar indication and is directed to a detachable balloon that could be used to occlude blood flow to a benign tumor or similar indication or for sealing an opening in the wall of a blood vessel or other percutaneous opening. The present invention is directed to a method for internally ligating vessels. The device and procedure could be used for occluding blood flow to a benign tumor, similar indication, or in support of vessel harvesting.

2. Background.

The recovery time for soft tissue surgery for stent placement is on average forty-seven days while the recovery time for catheteral placement is approximately eleven days. As catheteral procedures have improved and increased over the past decade, Interventional Radiology has developed as a specialized field of radiology in which the treatment of vascular and non-vascular diseases is accomplished through the use of small diameter catheters and the deployment of devices through small diameter catheters. Many of these catheteral procedures involve embolotherapy or hemostasis, which is a minimally invasive procedure that employs an embolic or blocking agent to a targeted vessel to inhibit blood flow to a tumor or similar indication. The present invention is

classified as a mechanical occlusion device. Similar devices include balloons, coils, and clamps.

Detachable balloons are mechanical devices that are used for embolotherapy. These balloons can vary in size and shape, and are typically manufactured from either latex or silicone. Detachable balloons can be inflated and left in place to form a permanent blockage and can also be used to provide a temporary blockage to prevent blood loss during surgical procedures. Although the balloons are self-sealing, over time they can deflate and can even migrate causing a blockage in nearby blood vessels.

Ligation of a blood vessel is another means to provide blood flow occlusion. Unfortunately, the lengthy recovery from soft tissue surgery eliminates ligation as a viable means to provide temporary and in some cases permanent occlusion of blood vessels. Ideally, a percutaneous means of tying-off blood vessels is required to support interventional radiological procedures. The present invention is directed to a method for internally ligating vessels. The device and procedure could be used for occluding blood flow to a benign tumor, similar indication, or in support of vessel harvesting.

SUMMARY OF THE INVENTION

The vaso-occluding stent of the present invention can be used to occlude blood flow to a benign tumor or similar indication. By slowly occluding blood flow, the post-procedural complications associated with some forms of embolotherapy will be reduced. The vaso-occluding stent of the present invention is deployed through a percutaneous catheteral procedure. The vaso-occluding stent of the present invention is designed to be used in conjunction with currently existing stents, such as Bolton Medical's "Spiral

Force" stent number 11-700-09. This Bolton Medical stent is 9 mm long and expands to a diameter of 2.5 to 4.0 mm. This Bolton Medical stent is compatible with Bolton Medical's "SF System" catheter, where the stent is preloaded onto a "Rapid Exchange PTCA Catheter." The vaso-occluding stent of the present invention could also be used with the Bolton Medical's stent number 20-250-9. In addition, the vaso-occluding stent of the present invention can be resized to function with any similarly functioning stent.

To minimize recovery with human patients, the vaso-occluding stent of the present invention does not require soft tissue surgery. Instead, a catheteral procedure is utilized to implant the device. Since the targeted vessels are typically small diameter vessels, the design of the vaso-occluding stent of the present invention resembles a short, flexible, small diameter tube, and is capable of being expanded and anchored on the inner wall of a vessel. The vaso-occluding stent of the present invention absorbs fluid from the blood stream and expands over a predetermined period of time. The vaso-occluding stent of the present invention can be designed for complete closure or to occlude to a predetermined point to allow a reduced level of blood flow. By controlling the rate of occlusion, side effects from abrupt changes in blood flow are eliminated.

The vaso-occluding stent of the present invention includes the following four components: (1) an expandable stent similar in size and function to an angioplasty stent, (2) casein powder which acts as an expandable filler material (3) stainless steel foil to promote the uniform expansion of the casein and (4) a barrier film that encapsulates the stent, filler and foil.

Casein is a milk by-product and is used as a component of the stent of the present invention because it is inert and will expand over time to slowly occlude blood flow

through the vessel. Casein has been incorporated into medical devices that are used in the field of veterinary medicine. The formation of an extra hepatic portosystemic shunt (EPSS) is a congenital condition in dogs and cats that is treated by surgically implanting an Ameroid Constrictor around the EPSS. The Ameroid Constrictor is composed of casein surrounded by a rigid, C-shaped stainless steel band and is placed around the outer wall of the EPSS. The casein material absorbs bodily fluids and slowly occludes the EPSS, thereby reducing the hypertension and promoting the replacement of blood vessels. Although casein is a viable material that has been proven in similar applications, any other inert material with similar solubility and mechanical properties would suffice.

The stent of the present invention can be manufactured either from stainless steel or from Elgiloy, an alloy of cobalt, chromium, nickel and iron. Elgiloy has superior mechanical properties as compared to stainless steel, and is preferred for use with the vaso-occluding stent of the present invention, because an Elgiloy stent will resist fracture or growth due to casein expansion.

Polypropylene (PP) has been selected as the material for the barrier film of the stent of the present invention. Additionally, other polymers such as Polytetrafluoroethylene (PTFE) and Polyethylene (PE) could be used provided their hydrophilic capacity is similar to that of PP. The hydrophilic capacity of all these materials could be modified/increased through the use of radiation grafting or surfactants.

The casein used in the stent of the present invention is pressure formed onto a thin sheet of stainless steel foil, and the casein/foil laminate is spirally wound. When the vaso-occluding stent of the present invention expands from the crimped state to the deployed state, the casein/foil laminate will unwind uniformly to reduce the risk of

fracture to the casein. The outer surfaces of the casein, i.e. the two sides and the inner diameter, are first to absorb fluid and expand. The core of the formed casein is smaller in comparison to the outer surface, and therefore, the expansion rate is greater for the first initial period and slows from that point until occlusion is complete. Unlike the Ameroid Constrictor, the vaso-occluding stent of the present invention is placed into the blood stream using a percutaneous catheteral procedure. The stent, foil and casein are completely encapsulated by a micro-porous PP film that acts as (1) a barrier to retain any casein particles that could separate during deployment and (2) to control the rate at which the casein will expand. This feature allows the occlusion rate to be optimized to support specific medical conditions, patient recovery and to minimize mortality. The PP barrier is heat sealed to provide hermetic encapsulation of the components of the vaso-occluding stent of the present invention.

The vaso-occluding stent of the present invention will be fixed in place using a minimally invasive procedure. Placement and setting of the vaso-occluding stent will transmit minimal force to the targeted vessel. The vaso-occluding stent will slowly occlude blood flow through the vessel, either completely or to a predetermined degree. The vaso-occluding stent and all the components of the vaso-occluding stent will be biocompatible and non-biodegradable. By design, the vaso-occluding stent will minimize localized infection and thrombosis, and provide a means to identify the post-procedural location.

The detachable balloon of the present invention includes the following five components: (1) a preformed, expandable balloon manufactured from latex or silicone or another elastomer with similar properties, (2) a septum manufactured from an elastomer

or another material with similar properties, to provide an ingress to the inside of the expandable balloon and a seal for the same, (3) a rigid band manufactured from stainless steel, Elgiloy, or a material with similar properties, to act as a sealing surface and to attach the septum to the expandable balloon and seal the device, (4) a crimp ring to fix and seal the balloon and septum to the rigid band assembly, and (5) a solution of saline and expandable particles, such as polyvinyl alcohol (PVA), gelatin foam, n-butyl-cyanoacrylate (nBCA) or a similar material, that are used to inflate the balloon.

Small PVA particles are commonly used to treat uterine fibroids. The surgical procedure for this condition begins by making a small incision near the groin to feed a catheter into the femoral artery. Using X-ray imaging, the catheter is directed near the target site. PVA particles are then injected through the catheter to the local area around the target site. The particles absorb fluid from the bloodstream to enlarge and form a blockage. The vessels at the target site are typically too small for the catheter to enter, and the PVA particles are therefore released some distance from the target site where they can migrate into other local vessels and cause unintended blockages. Also, the success of this form of embolic depends on the development of blood clotting around the PVA particles.

The detachable balloon of the present invention would be placed at a target site using a percutaneous catheteral procedure as described above. The present invention utilizes expandable particles as the media for inflating the expandable balloon. Once the device is in place, the solution is injected through the septum to completely expand the balloon and allow the balloon to anchor to the vessel wall. The balloon is sealed to eliminate the potential for deflation and migration. If a temporary blockage is required,

the particles can be removed with a larger syringe, thereby deflating the balloon. Depending on the starting size of the PVA particles, the full expansion can be determined to correctly size a larger syringe for particle removal.

The detachable balloon of the present invention can also be filled with saline or gas, which is currently a typical practice in the medical device industry. For this alternative, the sealing integrity of the septum can be greatly improved by the addition of a diaphragm. To incorporate this feature, the inside flat surface of the rigid band needs to be spherical and convex. The diaphragm is a thin flexible membrane that is stretched across the spherical surface of the rigid band, and conforms to the spherical surface of the rigid band to form a seal. The crimp ring maintains the tension on the diaphragm. The diaphragm has a series of pierced holes around the diameter that is sealed by the spherical surface. As gas is injected into the device, the increase in pressure between the septum and diaphragm causes the diaphragm to separate from the spherical surface, thereby creating a pathway for the gas to enter the balloon. Once the balloon has been inflated, and the injection process has stopped, the pressure differential within the balloon causes the diaphragm to seal against the spherical surface. The balloon can be deflated by either of the following two methods: (1) a needle can extend through both the septum and diaphragm and (2) a needle can extend through only the septum, and a plunger can then be extended to open the diaphragm. This second alternative could also be used to fill the balloon, while allowing the internal pressure of the balloon to be monitored during the inflation process.

The detachable balloon of the present invention can also be combined with an expanding stent to form a permanent, fixed embolic. For this alternative, the detachable

balloon of the present invention described above is produced with three equally spaced axial bands that are over-molded onto the stent during the molding process, to produce an integral balloon/stent sub-assembly.

Further, the above concept for the balloon stent can be modified as follows to meet the requirements of the casein-based vaso-occluding stent of the present invention: (1) the expandable balloon is manufactured from a permeable material, such as PP, PTFE, PE, or another polymer with similar properties and (2) the balloon is attached to the internal periphery of the stent by three equally spaced flexible, folding connector bands.

When the balloon stent, modified to meet the requirements of the casein-based vaso-occulating stent of the present invention, is deployed at the target site, the modified balloon stent is expanded to grip the inner wall of the vessel by inflating the balloon briefly with either a saline solution or gas. The balloon is immediately deflated and returns to the original diameter and shape. Since the balloon is manufactured from a microporous barrier material, permeation of fluid or gas through the membrane does not occur during the brief period when the balloon is inflated to anchor the stent to the vessel wall. Also, the external surface of the balloon and device can be coated with heparin, or another thromboresistant drug, that will provide additional resistance to the flow of gas or fluid from the inside of the balloon into the blood stream. Expandable particles, such as PVA, gelatin foam, nBCA or a similar material, are injected into the balloon, filling the balloon without any expansion beyond the original shape. The heparin coating will dissolve shortly after the device is deployed enabling serum from the bloodstream to penetrate the barrier material and expand the particles over time. Similar to the casein-

based vaso-occluding stent, the rate of occlusion is controlled by the porosity, both pore size and distribution, of the permeable balloon material.

The internal ligation device of the present invention is intended for use as part of a percutaneous catheteral procedure. The device includes the following six components: (1) non-absorbable monofilament or braided sutures, (2) sharpes to puncture the inner wall of the vessel, (3) slides to advance the sutures through the punctured holes, (4) a clamping mechanism to tie-off the sutures once the vessel is occluded, (5) cutting blades to sever the excess length of suture, and (6) a housing to retain the components and provide mechanical alignment for the ligation process. The sharp tips, cutting blades, and housing are manufactured from stainless steel or another material with similar properties. The clamping mechanism, the sharp sleeves, and the suture slides are manufactured from polypropylene or another polymer with similar properties.

The internal ligation device of the present invention would be placed at a target site using a percutaneous catheteral procedure as described above. Once in place, the sharps would be advanced from the catheter tip by the mechanical control of the interventional radiologist. The sharps are an integral part of the sharp sleeves and can be attached to the sharp sleeves by an insert molding operation or similar process. The sharp sleeves are molded into a curved shape, and they are flexed straight when assembled to and retained by the housing. When the sharp sleeves are extended from the housing, they return to their molded-in curvature. As they continue to extend from the housing, the sharps pierce the vessel wall adjacent to the housing end. The three sharps pierce the inner wall of the blood vessel at three evenly spaced points around the diameter.

The suture slides of the internal ligation device of the present invention are also molded from a flexible polymer. The thin cross-section of the suture slides allows them to easily conform to and follow the shape of the sharp sleeve. The ends of the sutures have preformed arms that have been folded back onto the length of each suture so that the folded end appears to be of slightly larger dimension as compared to the diameter of the remaining length of suture. The sutures are confined in the slides so that the suture arms remain folded back onto the length of the suture.

The suture slides of the internal ligation device of the present invention are advanced, through the sharp sleeves, and push the sutures through the holes in the vessel wall created by the sharps. Once the slides have pushed the sutures through the vessel wall, the arms of the sutures spring out to the preformed shape that extends significantly beyond the diameter of the hole in the vessel wall. The sharp sleeves and suture slides are retracted, and the sutures are pulled tightly to the clamping mechanism, thereby occluding the vessel. The excess length of suture is cut on the top surface of the clamping mechanism by the cutting blades.

The internal ligation device of the present invention could also be modified to allow the sutures to be cauterized rather than being clamped and cut. Another alternative would be to use a cauterizing operation to sever the sutures and bond the suture ends together, thereby eliminating the need for a clamping mechanism.

In summary, the following are the sequences of operations for the ligation of vessels with the internal ligation device of the present invention: (1) sharp sleeves and suture slides advance, (2) sharps pierce vessel wall, (3) suture slides continue to advance, (4) preformed sutures expand outside of the vessel wall, (5) suture slides retract to suture

release surfaces, (6) the suture releases shed the sutures, (7) suture slides and sharp sleeves retract inside device, (8) sutures are pulled tight, (9) cutting blades advance, and (10) sutures are cut on the top surface of the clamps.

The vaso-occluding devices previously described all follow a similar sequence for deployment and expansion. The device is deployed at the target site using a percutaneous catheteral procedure, and expanded to the maximum intended diameter. Occlusion is then accomplished as the internal components of the device expand inward to restrict blood flow. Unfortunately, the abrupt expansion of the device when first deployed can cause damage to the vessel and in some cases can cause the vessel to rupture. Conversely, the device can be designed so that the outer diameter expands slowly, thereby minimizing the potential for damage to the vessel.

For this alternative the original concept for the vaso-occluding device is modified in the following manner to allow both the outside and inside diameters to slowly transition to their final state where occlusion is complete. A similarly sized stainless steel foil that is of spring hardness replaces the wound, stainless steel foil band. The hardness and thickness of the stainless steel are adjusted to achieve the desired spring force. The foil is wound in a coil such that the natural or free state of the coil is slightly greater than the intended diameter of the expanded coil after occlusion is complete. Expansion of the coil beyond the intended diameter is restricted by the expanded barrier and vessel. Similar to the first embodiment described above, casein or another biocompatible material with similar expansion properties is bonded to the inside surface of the wound band. Superabsorbent polymers, such as sodium polyacrylate and polyacrylamide, can be used in place of casein. Superabsorbent polymers are hydrophilic cross-linked polymers

that will not dissolve in blood serum, but instead will absorb and retain fluid. The absorption rate and retention of superabsorbent polymers is controlled by modifying the degree of cross-linking in the surface of the material. Tighter cross-linking will result in slower diffusion / absorption of fluid into the material. For deployment, the band is wound to a smaller diameter and the subassembly composed of the band, casein, and stent is fixed at the smaller diameter by means of a polymer ring that fits tightly to the outer diameter of the stent. The mechanical properties, specifically the tensile strength, of the polymer or copolymer selected for these outer constraining rings diminishes over time due to exposure to the blood. The tensile strength of polyamides (PA) reduces over time with exposure to fluid. Other polymers and materials that behave similarly with exposure to blood protein, serum, enzymes, or changes in pH can also be used in this application. The constraining rings could also be manufactured from many of the natural and synthetic materials that are commonly used to produce absorbable sutures. These materials are used as homopolymers or copolymers and they include: glycolide, lactide, dioxanone, epsilon-caprolactone, and trimethylene carbonate. These materials are inert, noncollagenous, and nonantigenic, and their absorption cycle is characterized by a gradual loss of tensile strength followed by a loss of mass, until the material is completely absorbed. The cross-section of the outer constraining rings is sized so that the dry, as-molded rings can constrain the wound band at the tighter deployment diameter and to also control the duration of the expansion of the device. Similar to the original concept, the subassembly, composed of the casein, wound band, stent, and polymer rings, is encapsulated within a microporous barrier. The complete assembly is attached to a balloon and deployed at the target site with only minimal expansion to allow the device

to anchor to the inside of the vessel. As the polymer absorbs fluid from the bloodstream, the tensile strength reduces and the spring force of the wound band causes the diameter of the device to slowly expand. Concurrently, the casein expands reducing the inner diameter.

By removing the casein, this device can be used for vaso-dilation. Deployment would be identical to the process previously described, where a balloon is used to expand the device only a slight degree, but sufficiently to anchor the device to the vessel wall. As the constraining rings weaken from exposure to blood, the wound band will slowly expand the device, thereby dilating the vessel. This vaso-dilating concept and the similar vaso-occluding concept both provide slow expansion of the vessel to reduce the potential for rupture and damage, which can occur with abrupt expansion of a stent. This concept is described for use in conjunction with an angioplasty stent, but would still meet the design intent if implanted independently of the stent and barrier.

The same materials and components previously described above can be recombined in a variety of designs to produce other vaso-dilating concepts. For example, the stainless steel band can be replaced with a sintered stainless steel tube, or a tube made of another porous, biocompatible material. The sintered tube is formed into a ring with an opening in one end. The opposite end has a solid reduced diameter that fits into the open end to create an expanding ring. The tube is partially filled with casein or a superabsorbent polymer leaving sufficient space for the opposite end to engage into the open end and for expansion of the casein. The sintered material allows fluid to diffuse through the wall of the tubing so that the casein can expand. The round cross-section of the tubing provides sufficient hoop strength to direct the casein expansion toward the

open end of the tube, thereby causing the device to expand. Tubing with rectangular cross-section could be used, but the wall thickness would need to be greater to assure that the casein expansion did not result in tubing deformation. This concept can be used in conjunction with an angioplasty stent, but would still meets the design intent, i.e. vessel dilation, if implanted independently of the stent and barrier.

Increasing the number of expansion points is a means to further refine this concept and provide uniform expansion. This alternative could be achieved by constructing the ring from a series of links or ring segments. Each segment would be composed of sintered stainless steel or another biocompatible porous material, and would have an open end and a closed opposing end that has a reduced diameter. The closed end from each link would engage with the open end of the ensuing link, and the size and number of links would be determined by the vessel diameter at the target site.

Another concept for a vaso-dilating device would result from modifying the previously described wound band produced from spring grade stainless steel. The natural or free state of the band would be slightly greater than the intended, dilated diameter of the targeted vessel. Prior to forming the stainless steel into a wound band, the stainless steel material would have pockets either stamped or machined into the surface. The pockets on one side of the band would align sequentially with the pockets on the opposite side of the band, when the band is wound to the deployment diameter. For the wound band to be constrained to a smaller diameter, keys are placed in the series of pockets. The keys can be manufactured from any of the natural and synthetic materials that are commonly used to produce absorbable sutures. These materials are used as homopolymers or copolymers and they include: glycolide, lactide, dioxanone, epsilon-

caprolactone, and trimethylene carbonate. These materials are inert, noncollagenous, and nonantigenic, and their absorption cycle is characterized by a gradual loss of tensile strength followed by a loss of mass, until the material is completely absorbed. Materials with similar properties that are inert, biocompatible, and will dissolve from exposure to the bloodstream can also be used. The cross-section of the keys incrementally increases from pocket to pocket, so that the keys dissolve sequentially and there is a delay between each ensuing expansion of the band. The cross-section of the keys is rectangular to better resist the shear force produced by the wound band. Each pocket in the series is increasingly longer to include the expansion that occurs when the preceding key dissolves.

BRIEF DESCRIPTION OF DRAWINGS

These and other features, aspects and advantages of the present invention will become better understood with reference to the following description, appended claims, and accompanying drawings where:

FIGS. 1(a) - 1(c) show the cross-sections of the vaso-occluding stent of the present invention in the crimped state, deployed state, and expanded state, respectively.

FIG. 1(d) is a perspective view of the device.

FIGS. 2(a) and 2(b) show how to make the casein sub-assembly and insert the casein sub-assembly into the stent.

FIG. 3 shows how to form the polypropylene barrier and hermetically seal the vaso-occluding stent with the polypropylene barrier.

FIGS. 4(a) through 4(c) show the detachable balloon device of the present invention located at the target site, the inflation of the balloon with a solution of saline and particles, and the completely expanded particles, respectively. The ratio of saline to particles is balanced to allow nearly complete absorption of the fluid.

FIGS. 4(d) through 4(f) show a cross-sectional view of the diaphragm assembly with the diaphragm closed, a front view of the diaphragm assembly, and a cross-sectional view of the diaphragm assembly with the diaphragm open, respectively.

FIGS. 4(g) and 4(h) show the deflation of the balloon with a needle and the deflation of the balloon using a needle and plunger, respectively.

FIGS. 5(a) through 5(d) show the balloon device of the present invention located at the target site, the inflation of the balloon with the solution of saline and particles, and the completely expanded particles respectively. Similar to the removable, detachable balloon, the ratio of saline to particles is balanced to allow near complete absorption of the fluid.

FIGS. 6(a) through 6(c) show the balloon device of the present invention located at the target site, the balloon inflated with saline to anchor the stent to the vessel wall, the deflated balloon injected with particles, and the inflated balloon after the particles have expanded from absorbing serum from the blood, respectively.

FIGS. 7(a) and 7(b) show the shape of the suture of the internal ligation device of the present invention when retained in the slide.

FIG. 7(c) shows the unfolded suture arms.

FIGS. 7(d) through 7(f) show a cross-section of the device and identify the individual components.

FIGS. 7(g) through 7(p) show the sequential steps to the operation of the device.

FIG. 7(q) shows the ligated vessel.

FIG. 8(a) – 8(e) show a second embodiment of the vaso-occluding device as the device would be crimped to a balloon, in the deployed state, a state of partial expansion, the state of complete expansion, and the free state of the wound band, respectively.

Figures 9(a) – 9(e) show another embodiment, wherein the device is used for vaso-dilation, in the deployed state, a state of partial expansion, and the state of complete expansion, respectively.

Figures 10A – 10E show another embodiment, wherein the device is used for vaso-dilation, while crimped to a balloon, in the deployed state, a state of partial expansion, the state of complete expansion, and the free state of the wound band, respectively.

Figures 11(a) – 11(c) shows another device alternative in the deployed state, a state of partial expansion, and the state of complete expansion, respectively.

Figures 12(a) – 12(c) shows another vaso-dilating device embodiment in the deployed state, a state of partial expansion, and the state of complete expansion, respectively.

DESCRIPTION OF THE INVENTION

The first embodiment of the present invention is shown in FIGS. **1(a) – 1(d)**, the vaso-occluding stent **100** comprises an expandable stent **110** similar in size and function to an angioplasty stent, an expandable filler material, such as casein powder **120**, which

has been bonded to a thin sheet of foil **140**. The casein / foil subassembly is contained within the stent **110**, and a barrier film **130** encapsulates the stent **110**, the formed casein **120**, and the foil **140**. Casein is an ideal material because the preformed shape does not delaminate from the foil or crack as it expands. The vaso-occluding stent **100** is placed into the blood stream using a percutaneous catheteral procedure. When deployed, the barrier film **130** will expand to follow the deployed diameter of the stent. As the casein **120** expands, the inner diameter of the vaso-occluding stent **100** will decrease until blood flow is completely occluded. Therefore, the barrier film **130** must be able to stretch significantly without rupture.

The stent **110** can be manufactured from Elgiloy, an alloy of cobalt, chromium, nickel and iron. Elgiloy is commonly used for stents and has superior mechanical properties, such as the modulus of elasticity or stiffness, as compared to 316 stainless steel. Elgiloy provides a high level of hoop strength to assure that internal pressure from the casein will not cause further expansion of the stent and damage to the vessel wall.

The casein **120** expands over time to slowly occlude blood flow through the vessel. The casein **120** is pressure formed onto a thin sheet of stainless steel foil **140**, and the casein / foil laminate **120/140** is spirally wound, as shown in FIG. **1(a)**. When the vaso-occluding stent **100** expands from the crimped state (FIG. **1(a)**) to the deployed state (FIG. **1(b)**), the casein / foil laminate **120/140** will unwind uniformly. The foil **140** protects the formed casein from fracture as the vaso-occluding stent is deployed, and reduces the risk of fracture as the casein **120** expands. Without the foil **140**, the casein **120** would be driven through the stent **110** during deployment. Since expansion begins at the outer surface of the casein, the expansion rate is greater for the initial period and

slows from that point until occlusion is complete. Various types of casein **120** can be used in this application among these are kappa-casein glycomacropeptide (GMP), also known as caseinomacropeptide (CMP). This type of casein is soluble and can be pressure formed and bonded to the stainless steel foil **140**. However, any inert, biocompatible, soluble material with similar expansion and mechanical properties can be used in place of the casein.

The barrier film **130** that encapsulates the stent **110**, foil **140** and casein powder **120** act as a barrier to retain any casein particles that could separate during deployment and controls the rate at which the casein will expand. This feature allows the occlusion rate to be optimized to support specific medical conditions and patient recovery and minimize mortality. The barrier film **130** is a micro-porous polypropylene (PP) film that is wrapped completely around the stent **110** and casein powder **120** and foil **140**. The barrier film **130** is heat sealed to provide hermetic encapsulation of the components that comprise the vaso-occluding stent **100**. Heparin can be applied to the barrier film **130** to improve thromboresistance by either photoderivatizing and coupling the heparin to the surface of the polymer, or coating an ionically bonded heparin anitcoagulant onto the polymer. The use of PP as the barrier allows the vaso-occluding stent to be sterilized through radiation exposure.

Placement of a vaso-occluding stent has been designed as a percutaneous catheteral procedure to reduce recovery time. Depending on the targeted site, the placement procedure begins with a small incision either near the groin to access to the femoral artery or near the neck to access the jugular. A catheter is inserted into the major vessel and guided to the targeted site by means of dye and duplex sonography to identify

the location. A guide wire is then passed through the catheter, and the initial catheter tube is removed. The vaso-occluding stent is crimped onto a catheteral balloon and manipulated to the targeted vessel using the guide wire. For a larger diameter vessel, deployment can be completed using serial balloon angioplasty. For thromboresistance, heparin is administered to the site through the catheter following placement of the vaso-occluding stent. When used in conjunction with existing surgical procedures, the anti-thrombotic protocols typically used with those procedures will provide the same benefits to the vaso-occluding stent and the affected area of the vessel.

For use with the Bolton stent previously described, the outer diameter of the crimped stent is approximately 2.5 mm and the stent length is approximately 9.0 mm. When deployed, the stent diameter can expand from 3.5 to 6.0 mm in order to sufficiently expand and anchor to the inner wall of the vessel. In cases where the vessel diameter would require excessive elongation of the barrier, the vaso-occluding stent can be designed with additional barrier material on both ends. In other words, the stent would remain 9.0 mm long and the barrier would be 11.0 mm or longer. The diameter of the vaso-occluding stent can also be scaled to accommodate a larger diameter vessel. Shorter stents would be used to navigate a more tortuous route to the target site.

The expansion rate of the casein **120** is rapid initially and reduces over time until occlusion is complete. The pore size of the barrier film **130** is used to control the rate of expansion of the casein powder **120**. The maximum pore size should be no greater than 5 μm to avoid the ingress of bacteria. The pore size of the barrier film **130** can be adjusted below this value to create the desired rate of occlusion. The rate of occlusion also can be adjusted by changing the pore density of the barrier film. Although both PP and PTFE

are available as micro-porous films, PP is preferred to PTFE for this application for the following reasons: (1) the ability to be heat sealed or bonded to itself, (2) PP is more hydrophilic than PTFE to allow serum to pass from the blood stream and be absorbed by the casein, (3) the ability to be sterilized with radiation, and (4) PP is considered to be a viable polymer for providing thromboresistance. If necessary, the hydrophilic capacity of the PP can be increased through the use of surfactants or radiation grafting.

Fig. **2(a)** and **2(b)** show the method of making the casein sub-assembly and inserting the casein sub-assembly into the stent, respectively. As shown in Fig. **2(a)**, a roll of stainless steel **210** is unrolled through an embossing roll **220** to improve the bonding of casein thereto. Next, casein powder **230** is deposited from a bulk feeder **240** to the unwound stainless steel, and spread evenly on the sheet with a doctor blade **260**. Then, calendar rolls **270** pressure bond the casein powder to the stainless steel sheet. The casein/stainless steel sheet is cut to the proper width and rolled into individual coils.

As shown in FIG. **2b**, each individual coil **280** is unwound and fed to a spiral winder **250**. Before entering the spiral winder, the casein/stainless steel sheet is cut to the appropriate length and wound into a casein / foil subassembly by the spiral winder **250**. Then, the casein / foil **290** subassembly is inserted into the stent **295**. A spiral winder **250** used to produce constant force springs, battery electrodes or capacitors can be used.

FIG. **3** shows how to form the polypropylene barrier and hermetically seal the stent with the polypropylene barrier. As shown in FIG. **3**, a section of the polypropylene barrier **310** is unrolled and cut to the appropriate length. Next, the cut section of the polypropylene film is folded **320** and wound **330**, as shown in FIG. **3**. Then, a U-shaped seam **340** is ultrasonically welded into the barrier film and the casein foil subassembly is

inserted therein. Then, the resulting assembly **350** is ultrasonically welded to form a top seam **360**. Finally, the top seam is folded **370** into the inside to form a hermetically sealed stent.

The vaso-occluding stent design of the present invention provides a minimally invasive method to occlude blood flow through a vessel at a predetermined rate. The vaso-occluding stent can be designed to occlude blood flow at any rate from a few hours to several weeks. Numerous benefits are gained from occluding blood flow at a slow rate. Among these is the potential for the local tissue to revascularize in an effort to support increased blood flow, and the potential to reduce shock and cramps from the loss of localized blood flow.

The device of the present invention can be used to occlude blood flow to benign tumors or similar indications and could also be used as an alternative to the Ameroid Constrictor in animals. Also, the design can be modified to provide partial occlusion.

The second embodiment of the present invention **400** is shown in FIGS. **4-6**. The detachable balloon **400** of the present invention is comprised of five components: (1) a preformed, expandable balloon **420** manufactured from latex or silicone or another elastomer with similar properties, (2) a septum **430** manufactured from an elastomer or another material with similar properties to provide an ingress to the inside of the expandable balloon **420** and a seal for the same, (3) a rigid band **440** manufactured from stainless steel, elgiloy, or a material with similar properties, to act as a sealing surface and to attach the septum **430** to the expandable balloon **420** and seal the device, (4) a crimp ring **450** to fix and seal the balloon **420** and septum **430** to the rigid band **440** at assembly, and (5) a solution of saline and expandable particles **470**, such as polyvinyl

alcohol (PVA), gelatin foam, n-butyl-cyanoacrylate (nBCA) or a similar material, that are used to inflate the balloon **420** as shown in FIG. **4a** and **4b**.

The present invention would be placed at a target site using a percutaneous catheteral procedure as described above. The present invention utilizes expandable particles as the media for inflating the expandable balloon **420**. Once the device **400** is in place, the solution **470** is injected via a syringe **495** through the septum **430** to completely expand the balloon **420** and allow the balloon **420** to anchor to the vessel wall **490** as shown in FIG. **4b**. The balloon **420** is sealed to eliminate the potential for deflation and migration as shown in FIG. **4c**. If a temporary blockage is required, the particles can be removed with a larger syringe **495**, thereby deflating the balloon. Depending on the starting size of the PVA particles, the full expansion can be determined to correctly size a larger syringe **495** for particle removal.

The detachable balloon **420** of the proposed design can also be filled with saline or gas as is currently typical in the medical device industry. For this alternative, the sealing integrity of the septum **430** can be greatly improved by the addition of a diaphragm **480** as shown in FIG. **4d**. To incorporate this feature, the inside flat surface of the rigid band **440** needs to be spherical and convex. The diaphragm **480** is a thin flexible membrane that is stretched across the spherical surface of the rigid band **440**, and conforms to the spherical surface of the rigid band **440** to form a seal as shown in FIG. **4e**. The crimp ring **450** maintains the tension on the diaphragm **480**. The diaphragm **480** has a series of pierced holes **485** around a diameter that is sealed by the spherical surface as shown in FIG. **4d** and **4e**. As saline or gas is injected into the device the increase in pressure between the septum **430** and diaphragm **480** causes the diaphragm **480** to

separate from the spherical surface, thereby creating a pathway for the gas to enter the balloon **420** as shown in FIG. **4f**. Once the balloon **420** has been inflated, and the injection process has stopped, the pressure differential within the balloon **420** causes the diaphragm **480** to seal against the spherical surface. The balloon **420** can be deflated by either of two methods. A needle can extend through both the septum **430** and diaphragm **480** as shown in FIG. **4g**. Alternately, a needle can extend through only the septum **430**, and a plunger **496** can then be extended to open the diaphragm **480** as shown in FIG. **4h**. This second alternative could also be used to fill the balloon **420**, and to allow the internal pressure of the balloon **420** to be monitored during the inflation process.

The same concept can be combined with an expanding stent **410** to form a permanent, fixed embolic. For this alternative, the detachable balloon **420** described above is produced with three equally spaced axial bands **460** that are over-molded onto the stent **410** during the molding process, to produce an integral balloon **420**/ stent **410** sub-assembly as shown in FIG. **5a**.

The concept for the balloon **420** stent **410** can be modified as follows to meet the requirements of the casein-based vaso-occluding stent **100**. (1) The expandable balloon **420** is manufactured from a permeable material, such as polypropylene (PP), polytetraflouroethylène (PTFE), polyethylene (PE), or another polymer with similar properties. (2) The balloon **420** is attached to the internal periphery of the stent **410** by three equally spaced flexible, folding connector bands **460** as shown in FIG. **5a**.

When the device is deployed at the target site, the stent **410** is expanded to grip the inner wall of the vessel by inflating the balloon **420** briefly with either a saline solution **470** or gas as shown in FIG. **5b**. The balloon is immediately deflated and returns

to the original diameter and shape. Since the balloon **420** is manufactured from a microporous barrier material, permeation of fluid or gas through the membrane does not occur during the brief period when the balloon **420** is inflated to anchor the stent **410** to the vessel wall **490**. Also, the external surface of the balloon **420** and device **400** can be coated with heparin, or another thromboresistant drug, that will provide additional resistance to the flow of gas or fluid from the inside of the balloon **420** into the blood stream. Expandable particles, such as polyvinyl alcohol (PVA), gelatin foam, n-butyl-cyanoacrylate (nBCA) or a similar material, are injected into the balloon **420**, filling the balloon **420** without any expansion beyond the original shape as shown in FIG. **5c**. The heparin coating will dissolve shortly after the device **400** is deployed enabling serum from the bloodstream to penetrate the barrier material and expand the particles over time as shown in FIG. **5d**. Similar to the casein-based vaso-occluding stent **100**, the rate of occlusion is controlled by the porosity, both pore size and distribution, of the permeable balloon **420** material.

FIGS. **6a – 6d** show the device located at the target site, the balloon **420** inflated with saline to anchor the stent **410** to the vessel wall **490**, the deflated balloon **420** injected with particles, and the inflated balloon **420** after the particles have expanded from absorbing serum from the blood, respectively. FIGS. **5a – 5c** show the same device similarly deployed and with the balloon **420** immediately and fully expanded to provide complete immediate occlusion.

The third embodiment is shown in FIGS. **7a – 7r**. The internal ligation device **700** of the present invention is intended for use as part of a percutaneous catheteral procedure. The internal ligation device **700** is comprised of six components: (1) non-

absorbable monofilament or braided sutures **760**, (2) sharps **740** to puncture the inner wall of the vessel **490**, (3) slides **750** to advance the sutures through the punctured holes, (4) a clamping mechanism **780** to tie-off the sutures **760** once the vessel is occluded, (5) cutting blades **790** to sever the excess length of suture **760**, and (6) a housing **710** to retain the components and provide mechanical alignment for the ligation process as shown in FIG. **7d**. The sharps **740**, cutting blades **790**, and housing **710** are manufactured from stainless or another material with similar properties. The clamping mechanism **780**, the sharp sleeves **745**, and the suture slides **750** are manufactured from polypropylene or another polymer with similar properties.

The internal ligation device **700** housing **710** is placed at the target site using a percutaneous catheteral procedure as is known in the art. A user such as an interventional radiologist mechanically controls the internal ligation device by the use of plungers **791**, **792**, **793**, **794**, **795** as are known in the art and as are shown in FIG. **7r**. Once in place, as shown in FIG. **7g**, the sharps **720** are advanced from the catheter tip, as shown in FIG. **7h**, by the mechanical control of an interventional radiologist. The sharps **740** are an integral part of the sharp sleeves **745** and are attached to the sharp sleeves **745** through an insert molding operation or similar process. The sharp sleeves **745** are molded into a curved shape, and they are flexed straight when assembled to and retained by the housing **710** as shown in FIG. **7g**. When the sharp sleeves **745** are extended from the housing **710** the sharp sleeves **745** return to their molded-in curvature as shown in FIG. **7h**. As the sharp sleeves **745** continue to extend from the housing **710**, the sharps **740** pierce the vessel wall **490** adjacent to the housing **710** at evenly spaced points around the vessel perimeter FIG. **7h**. The suture slides **750** are also molded from a flexible polymer and

their thin cross-section allows them to easily conform to and follow the shape of the sharp sleeve **740**. The ends of the sutures **760** exposed outside of the suture slides **750** have preformed arms **770** which are folded back onto the suture **760** end, and when folded back appear to be of slightly larger dimension as compared to the diameter of the remaining length of the suture **760**. The suture arms **770** remain folded back onto the length of the suture **760** when confined in the suture slides **750** as shown in FIG. **7a** and **7b**. The suture slides **750** are advanced, through the sharp sleeves **745**, and push the sutures **760** through the holes in the vessel wall **490** created by the sharps **740** as shown in FIG. **7i**. Once the suture slides **750** have pushed the sutures **760** through the vessel wall, the arms **770** of the sutures **760** spring out, as shown in FIG. **7c**, to the preformed shape that extends significantly beyond the diameter of the hole in the vessel wall **490** as shown in FIG. **7j**. The sharp sleeves **745** and suture slides **750** are retracted as shown in FIGS. **7k-7m**, and the sutures **760** are pulled tightly to the clamping mechanism **780**, thereby occluding the vessel as shown in FIGS. **7p** and **7q**. The excess length of suture **760** is cut on the top surface of the clamping mechanism **780** by the cutting blades **790** as shown in FIG. **7n** and **7o**. The device **700** could also be modified to allow the sutures **760** to be cauterized rather than being clamped and cut. Another alternative would be to use a cauterizing operation to sever the sutures **760** and bond the suture **760** ends together, thereby eliminating the need for a clamping mechanism **780**.

FIGS. **8A – 8E** show a second embodiment of the vaso-occluding device that allows the outer diameter to expand slowly, thereby minimizing the potential for damage to the vessel. For this embodiment the original concept for the vaso-occluding device is modified in the following manner to allow both the outside and inside diameters to

slowly transition to their final state where occlusion is complete. A similarly sized stainless steel foil **840**, as shown in FIG. **8E**, that is of spring hardness replaces the wound, stainless steel foil band. The hardness and thickness of the stainless steel are adjusted to achieve the desired spring force. The foil is wound in a coil such that the natural or free state of the coil, as shown in FIG. **8E**, is slightly greater than the intended diameter of the expanded coil, as shown in FIG. **8D**, after occlusion is complete. Expansion of the coil beyond the intended diameter is restricted by the expanded barrier and vessel.

Casein **820** or another biocompatible material with similar expansion properties is bonded to the inside surface of the wound band as shown in FIG. **8A**. Superabsorbent polymers, such as sodium polyacrylate and polyacrylamide, can be used in place of casein. Superabsorbent polymers are hydrophilic cross-linked polymers that will not dissolve in blood serum, but instead will absorb and retain fluid. The absorption rate and retention of superabsorbent polymers is controlled by modifying the degree of cross-linking in the surface of the material. Tighter cross-linking will result in slower diffusion / absorption of fluid into the material. For deployment, the band is wound to a smaller diameter and the subassembly composed of the wound band **840**, casein **820**, and stent **810** is fixed at the smaller diameter by means of a polymer ring(s) **815** that fits tightly to the outer diameter of the stent **810** as shown in FIG. **8A**.

The mechanical properties, specifically the tensile strength, of the polymer or copolymer selected for these outer constraining rings diminishes over time due to exposure to the blood. The tensile strength of polyamides (PA) reduces over time with exposure to fluid. Other polymers and materials that behave similarly with exposure to

blood protein, serum, enzymes, or changes in pH can also be used in this application. The constraining ring(s) **815** could also be manufactured from many of the natural and synthetic materials that are commonly used to produce absorbable sutures. These materials are used as homopolymers or copolymers and they include: glycolide, lactide, dioxanone, epsilon-caprolactone, and trimethylene carbonate. These materials are inert, noncollagenous, and nonantigenic, and their absorption cycle is characterized by a gradual loss of tensile strength followed by a loss of mass, until the material is completely absorbed.

The cross-section of the outer constraining ring(s) **815** is sized so that the dry, as-molded rings can constrain the wound band at the tighter deployment diameter and to also control the duration of the expansion of the device. Similar to the original concept, the subassembly, composed of the casein **820**, wound band **840**, stent **810**, and polymer ring(s) **815**, is encapsulated within a microporous barrier **830**. The complete assembly is attached to a balloon and deployed at the target site with only minimal expansion to allow the device to anchor to the inside of the vessel as shown in FIG. **8B**. As the polymer ring(s) **815** absorbs fluid from the bloodstream, the tensile strength reduces and the spring force of the wound band causes the diameter of the device to slowly expand as shown in FIG. **8C-8D**. Concurrently, the casein **820** expands reducing the inner diameter.

By removing the casein, this device can be used for vaso-dilation, as shown in FIGS. **9A – 9C**. The device of this embodiment is composed of only four components: the stent **910**, the constraining ring(s) **915**, the microporous barrier **930**, and the wound stainless steel band **940** as shown in FIG. **9A**. Deployment would be identical to the process previously described, where a balloon is used to expand the device only a slight

degree, but sufficiently to anchor the device to the vessel wall as shown in FIG. **9B**. As the constraining ring(s) **915** weaken from exposure to blood, the wound band will slowly expand the device, thereby dilating the vessel as shown in FIG. **9C**. This vaso-dilating concept and the similar vaso-occluding concept both provide slow expansion of the vessel to reduce the potential for rupture and damage, which can occur with abrupt expansion of a stent. This concept is described for use in conjunction with an angioplasty stent **910**, but would still meet the design intent, i.e. vessel dilation, if implanted independently of the stent **910** and barrier **930**.

FIGS. **10A – 10E** show this same device without the stent and barrier. The device shown in FIGS. **10A – 10E** is composed of only two components: the constraining rings **1015** and the wound stainless steel band **1040**. In FIG. **10D**, the constraining ring(s) **1015** has been dissolved allowing the wound band **1040** to expand completely.

The same materials and components previously described above can be recombined in a variety of designs to produce other vaso-dilating concepts. As shown in FIGS. **11A – 11C**, the stainless steel band can be replaced with a sintered stainless steel tube **1125**, or a tube made of another porous, biocompatible material. The sintered tube is formed into a ring with an opening **1130** in one end as shown in FIG. **11A**. The opposite end has a solid reduced diameter **1135** that fits into the open end to create an expanding ring. The tube is partially filled with casein **1120** or a superabsorbent polymer leaving sufficient space for the opposite end to engage into the open end and for expansion of the casein. The vaso-dilating device may also incorporate a hygroscopic polymer. The sintered material allows fluid to diffuse through the wall of the tubing so that the casein can expand. The round cross-section of the tubing provides sufficient

hoop strength to direct the casein expansion toward the open end of the tube, thereby causing the device to expand as shown in FIG. **11C**.

Tubing with rectangular cross-section could be used, but the wall thickness would need to be greater to assure that the casein expansion did not result in tubing deformation. This concept can be used in conjunction with an angioplasty stent, but would still meet the design intent, i.e. vessel dilation, if implanted independently of the stent and barrier. Deployment would be identical to the process previously described, where a balloon is used to expand the device only a slight degree, but sufficiently to anchor the device to the vessel wall as shown in FIG. **11B**.

Another embodiment results from modifying the previously described wound band **1240** produced from spring grade stainless steel. The natural or free state of the band would still be slightly greater than the intended, dilated diameter of the targeted vessel. Prior to forming the stainless steel into a wound band **1240**, the stainless steel material would have pockets **1280** either stamped or machined into the surface. The pockets **1280** on one side of the band would align sequentially with the pockets **1290** on the opposite side of the band, when the band is wound to the deployment diameter as shown in FIG. **12A**. For the wound band **1240** to be constrained to a smaller diameter, keys **1250**, **1260**, and **1270** are placed in the series of pockets **1280, 1290**. The keys **1250**, **1260**, and **1270** can be manufactured from any of the natural and synthetic materials that are commonly used to produce absorbable sutures. These materials are used as homopolymers or copolymers and they include: glycolide, lactide, dioxanone, epsilon-caprolactone, and trimethylene carbonate. These materials are inert, noncollagenous, and nonantigenic, and their absorption cycle is characterized by a

gradual loss of tensile strength followed by a loss of mass, until the material is completely absorbed. Materials with similar properties that are inert, biocompatible, and will dissolve from exposure to the bloodstream can also be used. Examples of such material are adhesives such as cyanoacrylate. The cross-section of the keys **1250, 1260,** and **1270** incrementally increases from pocket **1280, 1290** to pocket **1280, 1290,** so that the keys **1250, 1260,** and **1270** dissolve sequentially and there is a delay between each ensuing expansion of the wound band **1240**. FIG. **12A** shows all three keys **1250, 1260,** and **1270** in place when the device is first deployed. FIG. **12B** shows the device after the first key **1250** has dissolved. FIG. **12C** shows the device after all three keys **1250, 1260,** and **1270** have dissolved. The cross-section of the keys **1250, 1260,** and **1270** is rectangular to better resist the shear force produced by the wound band. Each pocket **1280, 1290** in the series is increasingly longer to include the expansion that occurs when the keys **1250, 1260,** and **1270** dissolve consecutively.

The materials, the design of components and the various concepts described herein do not capture all the design alternatives that could result from an intensive evaluation of these inventions. From the detail shown, one skilled in the art would be able to derive similar concepts for both vaso-occluding and vaso-dilating devices. Similar concepts of this type and design should be protected by the embodiment.